CLAIMS

We claim:

1. A sustained release oral dosage form comprising a liquid antiviral drug composition which composition is substantially free of *in-situ* aggregation effect of the antiviral drug and provides substantially improved bioavailability of said antiviral drug.

2. The dosage form of claim 1 which administers a therapeutically effective dose of said antiviral drug over a period of at least 4 hours after oral administration with no more than 30% by weight of said drug composition being released within the first 1 hour after oral administration.

3. The dosage form of claim 1 which administers a therapeutically effective dose of said antiviral drug over a period of at least 12 hours after oral administration with no more than 30% by weight of said drug composition being released within the first 4 hours after oral administration.

4. The dosage form of claim 1 which administers a therapeutically effective dose of said antiviral drug over a period of 24 hours after oral administration with no more than 30% by weight of said drug composition being released within the first 12 hours after oral administration.

5. The dosage form of claim 1 comprising:

(a) a wall defining a compartment, the wall comprising a semipermeable layer;

(b) an expandable layer located within the compartment and in fluid communication with the semipermeable layer;

(c) a capsule located within the compartment and in direct or indirect contacting relationship with the expandable layer, the capsule comprising said liquid antiviral drug composition; and

(d) an exit orifice formed or formable in the dosage form extending from the external surface of the capsule to the environment of use.

6. The dosage form of claim 5 wherein the expandable layer is located within the capsule and is remote from the exit orifice.

7. The dosage form of claim 6 further comprising a barrier layer located within the capsule between the antiviral drug composition and the expandable layer.

8. The dosage form of claim 5 wherein the expandable layer is located within the compartment between the capsule and the semipermeable layer.

9. The dosage form of claim 8 further comprising a barrier layer located within the compartment between the capsule and the expandable layer.

10. The dosage form of claim 5 wherein said semipermeable layer comprises a semipermeable polymer; and the expandable layer comprises a hydrophilic polymer and optionally an osmotically effective compound.

11. The dosage form of claim 10 wherein the expandable layer further comprises a lubricant.

12. The dosage form of claim 11 wherein said hydrophilic polymer is present in the amount of about 0 wt% to about 95 wt%; the osmotically effective agent is present in the amount of about 0 wt% to about 60 wt%; and the lubricant is present is about 0 wt% to about 5 wt% of the total composition of the expandable layer.

13. The dosage form of claim 1 wherein the liquid antiviral drug composition comprises an antiviral drug solubilized in a solvent.

14. The dosage form of claim 13 wherein said solvent comprises a surfactant, an oil or mixtures thereof.

15. The dosage form of claim 14 wherein said surfactant is a non-ionic surfactant.

16. The dosage form of claim 14 wherein said liquid antiviral drug composition further comprises a hydrogel and optionally an osmagent.

17. The dosage form of claim 13 wherein said antiviral drug is present in an amount of about 5 wt% to about 60 wt% and the solvent is present in an amount of about 20 wt% to 95 wt% of the total antiviral drug composition.

18. The dosage form of claim 13 wherein the antiviral drug is selected from the group consisting of acyclovir, azidouridine, anasmycin, amantadine, bromovinyldeoxusidine, chlorovinyldeoxusidine, cytarbine, didanosine, deoxynojirmycin, dideoxycitidine, dideoxyinosine, dideoxynudeoside, desciclovir, deoxyacyclovir, edoxuidine, enviroxime, fiacitabine, foscarnet, fialuridine, fluorothymidine, fluxuridine, ganciclovir, hypericin, interferon, interlenkin, isethionate, idoxuridine, nevirapine, pentamidine, ribavirin, rimantadine, stavirdine, sargramostin, suramin, trichosanthin, trifluorothymidine, tribromothymidine, trichlorothymidine, vidarabine, zidoviridine, zalcitabine and 3-azido-3-deoxythymidine.

19. The dosage form of claim 14 wherein said antiviral drug is a protease inhibitor.

20. The dosage form of claim 19 wherein said protease inhibitor is selected from the group consisting of saquinavir, adefovir, ritonavir, indinavir, nelfinavir, amprenavir, zidovudine and zalcitabin.

21. A sustained release oral dosage form comprising a gelatin capsule comprising a liquid antiviral drug composition which composition is substantially free of *in-situ* aggregation effect of the antiviral drug and provides substantially improved bioavailability of said antiviral drug; an exit orifice formed or formable in the dosage form extending from the external surface of the gelatin capsule to the environment of use; an expandable layer located within the capsule and remote from the exit orifice; a semipermeable layer surrounding the external surface of the capsule; and optionally a barrier layer located within the compartment between the capsule and the expandable layer.

22. A sustained release oral dosage form comprising a gelatin capsule comprising a liquid antiviral drug composition which composition is substantially free of *in-situ* aggregation effect of the antiviral drug and provides substantially improved bioavailability of said antiviral drug; an expandable layer contacting the external surface of the gelatin capsule; a semipermeable layer surrounding the expandable layer; an exit orifice formed or formable in the dosage form extending from the external surface of the gelatin capsule to the environment of use; and optionally a barrier layer located within the capsule between the antiviral drug composition and the expandable layer.

23. The dosage form of claim 21 or claim 22 for use in treating a condition in a subject responsive to the antiviral drug, wherein said condition is acquired immune deficiency syndrome (AIDS) associated with human immunodeficiency virus (HIV) infection in the subject.

24. The dosage form of claim 23 which administers a therapeutically effective dose of said antiviral drug over a period of at least 4 hours after oral administration with no more than 30% by weight of said liquid composition being released within the first 1 hour after oral administration.

25. The dosage form of claim 23 which administers a therapeutically effective dose of said antiviral drug over a period of at least 12 hours after oral administration with no more than 30% by weight of said liquid composition being released within the first 4 hours after oral administration.

26. The dosage form of claim 23 which administers a therapeutically effective dose of said antiviral drug over a period of 24 hours after oral administration with no more than 30% by weight of said liquid composition being released within the first 12 hours after oral administration.

27. A pharmaceutical composition comprising a liquid antiviral drug formulation in a sustained release dosage form, wherein said composition is substantially free of *in-situ* aggregation effect of the antiviral drug and provides substantially improved bioavailability of said antiviral drug.

28. The pharmaceutical composition of claim 27 wherein the dosage form is adapted to administer a therapeutically effective dose of said antiviral drug over a period of at least 4 hours after oral administration with no more than 30% by weight of said liquid composition being released within the first 1 hour after oral administration.

29. The pharmaceutical composition of claim 27 wherein the dosage form is adapted to administer a therapeutically effective dose of said antiviral drug over a period of at least 12 hours after oral administration with no more than 30% by weight of said liquid composition being released within the first 4 hours after oral administration.

30. The pharmaceutical composition of claim 27 wherein the dosage form is adapted to administer a therapeutically effective dose of said antiviral drug over a period of 24 hours after oral administration with no more than 30% by weight of said liquid composition being released within the first 12 hours after oral administration.

31. The pharmaceutical composition of claim 23 wherein the liquid antiviral drug formulation comprises an antiviral drug solubilized in a solvent.

32. The pharmaceutical composition of claim 31 wherein said solvent comprises a surfactant, an oil or mixtures thereof.

33. The pharmaceutical composition of claim 32 wherein said surfactant is a non-ionic surfactant.

34. The pharmaceutical composition of claim 32 further comprising a hydrogel and optionally an osmagent.

35. The pharmaceutical composition of claim 33 wherein said antiviral drug is present in an amount of about 5 wt% to about 60 wt% and the solvent is present in an amount of about 20 wt% to 95 wt% of the total antiviral drug composition.

36. The pharmaceutical composition of claim 31 wherein the antiviral drug is selected from the group consisting of acyclovir, azidouridine, anasmycin, amantadine, bromovinyldeoxusidine, chlorovinyldeoxusidine, cytarbine, didanosine, deoxynojirmycin, dideoxycitidine, dideoxyinosine, dideoxvnudeoside, desciclovir, deoxyacyclovir, edoxuidine, enviroxime, fiacitabine, foscarnet, fialuridine, fluorothymidine, fluxuridine, ganciclovir, hypericin, interferon, interlenkin, isethionate, idoxuridine, nevirapine, pentamidine, ribavirin, rimantadine, stavirdine, sargramostin, suramin, trichosanthin, trifluorothymidine, tribromothymidine, trichlorothymidine, vidarabine, zidoviridine, zalcitabine and 3-azido-3-deoxythymidine.

37. The pharmaceutical composition of claim 32 wherein said antiviral drug is a protease inhibitor.

38. The pharmaceutical composition of claim 37 wherein said protease inhibitor is selected from the group consisting of saquinavir, adefovir, ritonavir,

indinavir, nelfinavir, amprenavir, zidovudine and zalcitabin.

39. A method of treating a condition in a subject responsive to antiviral medication, the method comprising orally administering to the subject a sustained release dosage form comprising an antiviral drug composition wherein said composition is substantially free of *in-situ* aggregation effect of the antiviral drug and provides substantially improved bioavailability of said antiviral drug.

40. The method of claim 39 wherein said dosage form administers a therapeutically effective dose of said antiviral drug over a period of at least 4 hours after oral administration with no more than 30% by weight of said liquid composition being released within the first 1 hour after oral administration.

41. The method of claim 39 wherein said dosage form administers a therapeutically effective dose of said antiviral drug over a period of at least 12 hours after oral administration with no more than 30% by weight of said liquid composition being released within the first 4 hours after oral administration.

42. The method of claim 39 wherein said dosage form administers a therapeutically effective dose of said antiviral drug over a period of 24 hours after oral administration with no more than 30% by weight of said liquid composition being released within the first 12 hours after oral administration.

43. The method of claim 39 wherein said dosage form comprises a gelatin capsule comprising a liquid antiviral drug composition which composition is substantially free of *in-situ* aggregation effect of the antiviral drug and provides substantially improved bioavailability of said antiviral drug; an exit orifice formed or formable in the dosage form extending from the external surface of the gelatin capsule to the environment of use; an expandable layer located within the capsule and remote from the exit orifice; a semipermeable layer surrounding the external surface of the capsule; and optionally a barrier layer located within the compartment between the capsule and the expandable layer.

44. The method of claim 39 wherein said dosage form comprises a gelatin capsule comprising a liquid antiviral drug composition which composition is substantially free of *in-situ* aggregation effect of the antiviral drug and provides substantially improved bioavailability of said antiviral drug; an expandable layer contacting the external surface of the gelatin capsule; a semipermeable layer surrounding the expandable layer; an exit orifice formed or formable in the dosage form extending from the external surface of the gelatin capsule to the environment of use; and optionally a barrier layer located within the capsule between the antiviral drug composition and the expandable layer.

45. The method of claim 43 or claim 44 wherein said dosage form produces an average steady-state plasma concentration of the antiviral drug greater than the therapeutically effective concentration of the antiviral drug over a period of about 4 hours to about 24 hours.

46. The method of any one of claims 39-44 wherein the antiviral drug composition comprises an antiviral drug solubilized in a solvent.

47. The method of claim 46 wherein said solvent comprises a surfactant, an oil or mixtures thereof.

48. The method of claim 47 wherein said surfactant is a non-ionic surfactant.

49. The method of claim 47 wherein said antiviral drug composition further comprises a hydrogel and optionally an osmagent.

50. The method of claim 46 wherein said antiviral drug is present in an amount of about 5 wt% to about 60 wt% and the solvent is present in an amount of about 20 wt% to 95 wt% of the total antiviral drug composition.

51. The method of claim 50 wherein said antiviral drug is a protease inhibitor.

52. The method of claim 51 wherein said protease inhibitor is selected from the group consisting of saquinavir, adefovir, ritonavir, indinavir, nelfinavir, amprenavir, zidovudine and zalcitabine.